

**COLD PLUS HEAD CONGESTION NIGHTTIME- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet, coated**  
**TopCo Associates LLC**

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**TCR - 1161 - 2019-1016**

***Drug Facts***

<b><i>Active ingredients (in each caplet)</i></b>	<b><i>Purpose</i></b>
Acetaminophen 325 mg	Pain reliever/fever reducer
Chlorpheniramine maleate 2 mg	Antihistamine
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses**

- for the temporary relief of the following cold symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion
  - runny nose and sneezing
  - cough
  - sinus congestion and pressure
- helps clear nasal passages
- relieves cough to help you sleep
- temporarily reduces fever

**Warnings**

**Liver warning**

This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy alert**

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening

- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

### **Sore throat warning**

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

### **Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

### **Ask a doctor before use if you have**

- liver disease
- high blood pressure
- heart disease
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

### **Ask a doctor or pharmacist before use if you are**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

### **When using this product**

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

### **Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present

- new symptoms occur
- cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition.

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.**

### Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### Directions

- do not take more than directed (see overdose warning)

adults and children 12 years and over	<ul style="list-style-type: none"> <li>▪ take 2 caplets every 4 hours</li> <li>▪ swallow whole – do not crush, chew, or dissolve</li> <li>▪ do not take more than 10 caplets in 24 hours</li> </ul>
children under 12 years	<ul style="list-style-type: none"> <li>▪ ask a doctor</li> </ul>

### Other information

- store between 20-25C (68°-77°F) in a dry place
- retain carton for complete product information and warnings

### Inactive ingredients

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

### PRINCIPAL DISPLAY PANEL

NDC 36800-925-02

TopCare® Health

NIGHTTIME

Cold + Head Congestion Nighttime

ACETAMINOPHEN, DEXTROMETHORPHAN HBr, PHENYLEPHRINE HCl, CHLORPHENIRAMINE MALEATE

# PAIN RELIEVER/FEVER REDUCER, COUGH SUPPRESSANT, NASAL CONGESTION, ANTIHISTAMINE

Relief of:

- Headache + Body Aches
- Fever + Sore Throat
- Cough
- Nasal Congestion
- Runny Nose

24 COOL TASTE CAPLETS



## COLD PLUS HEAD CONGESTION NIGHTTIME

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-925
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3SJ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>	MINT	<b>Imprint Code</b>	AAA;1139
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-925-02	2 in 1 CARTON	08/30/2011	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M012	08/30/2011	

**Labeler** - TopCo Associates LLC (006935977)

Revised: 12/2024

TopCo Associates LLC